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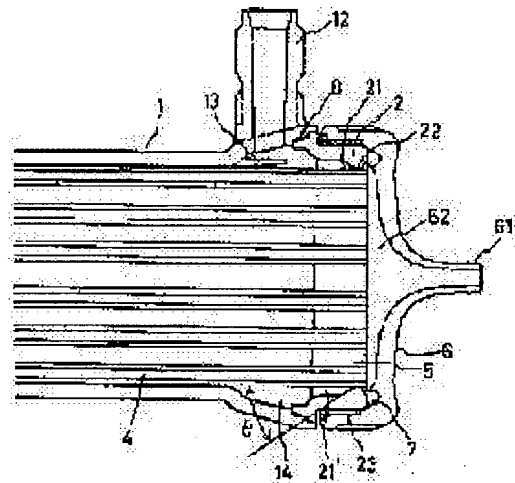
(72)Inventor : NAKAMATSU OSAMU
NIIMOTO YASUHIKO

(54) HOLLOW YARN MODULE AND ITS PRODUCTION

(57)Abstract:

PROBLEM TO BE SOLVED: To obtain a hollow yarn module smaller in the number of stagnated areas and size by the miniaturization of a header, low in cost and having good dimensional accuracy by bonding the end member of a case having a yarn bundle prescribing part and a header bonding part to the end part of a case body member.

SOLUTION: A header member 6 is bonded to a main body case in a liquid-tight state through an annular packing. The end member of a case has a yarn bundle prescribing part 22 prescribing the outer shape of hollow yarn bundles 4 and the header bonding part 23 engaged with the header member 6 and is bonded to a case body member 1 in a liquid-tight state by an ultrasonic bonding part 8. A yarn bundle guide part 21 to which an angle θ of inclination for inserting yarn bundles is provided is provided to the end member 2 of the case. The yarn bundle prescribing part 22 is rounded so as not to damage yarn bundles and pref. allowed to approach the hollow yarn opening surface provided to a partition wall 5 to the utmost so as to be capable of sufficiently developing its dimension prescribing effect.



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CLAIMS

[Claim(s)]

[Claim 1] It is a ***** hollow filament bunch about two or more hollow filaments. Case drum section material which has tubed idiosoma equipped with a side nozzle which contains this hollow filament bunch and is open for free passage to a peripheral face of this hollow filament bunch A septum which fixed the edges of said case drum section material and said hollow filament bunch in the condition of carrying out the opening of the ends of said hollow filament bunch An edge nozzle It is the hollow fiber module equipped with the above, and is characterized by joining case edge material which has a header joint for engaging with a thread bundle regulating part which regulates an appearance configuration of said hollow filament bunch, and said header material at least to said case drum section material edge.

[Claim 2] A bore (D1) of said thread bundle regulating part is a hollow fiber module according to claim 1 characterized by there being a value of a constant k expressed with the following type within limits which satisfy the range of 0.45-0.55.

$k = d_2 \times n / D_1^2$ however an outer diameter (micrometer) of d: hollow filament, n: A number of a hollow filament [Claim 3] A hollow fiber module according to claim 1 to 2 characterized by preparing a thread bundle guide part in said case edge material.

[Claim 4] A hollow fiber module according to claim 1 to 3 characterized by having an annular seal member and making variation of tolerance (D2-D1) of a bore (D2) of this annular seal member, and a bore (D1) of said thread bundle regulating part into the range of 0.5mm - 1.5mm between said case edge material and header joints.

[Claim 5] A hollow fiber module according to claim 1 to 4 with which said case drum section material and said case edge material are characterized by being obtained by injection molding.

[Claim 6] A hollow fiber module according to claim 1 to 5 with which said case drum section material and said case edge material are characterized by being joined by ultrasonic bonding.

[Claim 7] A hollow fiber module according to claim 1 to 6 characterized by using for blood purification.

[Claim 8] A dialyzer characterized by incorporating a hollow fiber module according to claim 1 to 7.

[Claim 9] To both ends of case drum section material which has tubed idiosoma equipped with a side nozzle After joining case edge material which has at least a thread bundle regulating part and a header joint which regulate an appearance configuration of said hollow filament bunch and assembling a main part case, Two or more hollow filaments are inserted in this main part case. Each edge of this hollow filament A manufacture method of a hollow fiber module characterized by joining header material which formed a septum to which adhesion immobilization was carried out with a sealing agent at this main part case, and the opening of this hollow filament is carried out, and was equipped with an edge nozzle subsequently to both ends of this main part case.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[The technical field to which invention belongs] This invention relates to the hollow fiber module used for the objects, such as blood purification, dialysis, or an ultrafiltration, and its manufacture method.

[0002]

[Description of the Prior Art] The hollow fiber module is widely used for an artificial kidney, an artificial liver, an artificial lung, plasma skimming, the ultrafiltration, the water purifier, etc., and is better known than before about many operation gestalten and various uses.

[0003] Like a publication, it is loaded with many hollow filaments into a tubed main part case, the edge of this hollow filament bunch is supported by the edge of this case by the septum member of the polymeric materials by which restoration solidification is carried out, and, as for these hollow fiber modules, the opening of the opening of each hollow filament is carried out to the outer edge surface of this septum member at JP,63-52522,B. And the header which surrounds the whole opening of each hollow filament is put on the both ends of this case, the nozzle for A liquid (for example, blood) which is open for free passage to opening of each hollow filament is prepared in this header, and the side nozzle for B liquid (for example, dialysing fluid) which attends the perimeter of this hollow filament bunch is prepared in the side of this case.

[0004] the basic structure mentioned above in the above-mentioned hollow fiber module to what is used especially for a medical field -- in addition, further very many demands are advanced.

[0005] Such a demand is related with layout of the hollow filament and case to be used. The class of hollow filament to be used can use not the object of this invention but the hollow filament of various classes. To the case, the following demands are especially advanced besides an obvious demand like the physical safety of a material, disinfectant, and reliability.

[0006] Here, A liquid which flows through the interior of a hollow filament is blood generally supplied to a hollow fiber module by extracorporeal circulation. Therefore, it is important that it is as much as possible small, the capacity filled by blood within a hollow fiber module, i.e., a blood room. Moreover, the blood room is important in order to make it the thing which receive a hollow filament and which is formed so that smooth floating distribution may be performed as much as possible, without producing the not much big stagnation section not make blood solidify.

[0007] At the time of operation of a module, it is important for the space where B liquid (for example, dialysing fluid) containing the harmful matter removed from blood exists and which surrounds a hollow filament to be formed so that a case may be loaded with many hollow filaments as much as possible so that this liquid may be as much as possible possible for whenever [high impregnation] in a structure format compact [flowing down to homogeneity] to a hollow filament outside surface that is,. For this reason, usually it provides between a case and the outside of a hollow filament bunch so that a baffle may be arranged directly under [introductory passage] the side nozzle for B liquid, it may be made for B liquid not to be equivalent to a hollow filament directly generally and B liquid can distribute to the whole hollow filament bunch, annulus ring-like space, i.e., B liquid induction.

[0008] Finally, it is required that a medical-application hollow fiber module can be cheaply manufactured after satisfying all requiring points the optimal as much as possible. Especially this is important. Generally, the cost of a medical-application hollow fiber module is because it has very remarkable effect on the cost of the medical care carried out by this module.

[0009] Moreover, generally an above-mentioned hollow fiber module is manufactured by the centrifugal potting method in many cases. That is, in the above-mentioned hollow fiber module, by preparing a septum member in a case, the activity which supports a hollow filament bunch, i.e., a potting activity, prepares the hollow filament of a large number longer than the length of this case first, and it locates this hollow filament bunch in a case. And the way side edge section is sealed outside this case by attaching the cap for potting in the outer edge surface of a case. Polymeric materials (potting material) are slushed from the side nozzle for B liquid prepared in the side of a case while rotating this case in the condition of placing the medial axis of a case on a radius of gyration. The above-mentioned potting material is centralized on the septum formation part of the way side edge section outside the shaft orientations of a case under a centrifugal force. It replaces so that the air which existed in the way side edge section outside the case sealed with this cap may be driven out in the above-mentioned potting material, and a septum is formed by the potting material solidification after predetermined time progress. After this potting material solidification, this septum slices the heel with a sharp cutter, and exposes the opening edge of a hollow filament on a front face. then, the header for forming a blood room in the both ends of a case -- liquid -- the gestalt as a hollow fiber module is acquired by attaching densely.

[0010]

[Problem(s) to be Solved by the Invention] Since annular space was prepared between the outsides of a case and hollow filament bunch so that B liquid could distribute to the whole hollow filament bunch by B liquid induction at abbreviation homogeneity, as a certain hollow fiber module was mentioned above from such the former, although the hollow fiber module could be obtained by the method mentioned above, and the baffle is formed directly under the installation passage of the side nozzle for B liquid, the path of the 2nd liquid induction is large from the path of the idiosoma of a main part case inevitably. The path of case both ends which has prepared B liquid induction conventionally also becomes larger than the path of this idiosoma for such structure. Therefore, the path of the header attached in case both ends also became large, and it had become the origin which increases abolition cost remarkably by enlargement of the whole hollow fiber module.

[0011] Moreover, since it is generally introduced from the center section of the header in case A liquid, i.e., blood, is introduced inside a hollow filament especially through a header with a medical-application hollow fiber module in this case, the blood rate of flow of the periphery section of the blood room in a header becomes small. When especially a header is large, it is in the inclination for the difference of the blood rate of flow to be expanded. When the delay of these blood rate of flow occurs, displacement efficiency or clarification effectiveness will fall and the engine performance as a hollow fiber module will fall.

[0012] Moreover, with this conventional structure, by the septum section in which the hollow filament is carrying out the opening, as soon as controlling the outer diameter of the whole hollow filament bunch uniformly spreads in difficulty. Since the shape of an appearance of the whole hollow filament bunch in a septum section hollow filament effective area becomes an abbreviation ellipse form or it inclines, it is necessary to take the big path clearance more than fixed, and to install an O ring between a header bore and the periphery portion of the whole hollow filament bunch. Since the flow of the blood of the above-mentioned path clearance portion and its neighborhood section became late with such structure and it became easy to produce **** by stagnation of a blood flow, to improve further was desired strongly.

[0013] JP,56-168807,A, JP,59-137062,A, JP,63-9448,A, or announcement JP,60-500083,A is proposed until now that these should be improved.

[0014] However, since the method of attaching in a case edge the ring which converges a thread which is indicated by JP,56-168807,B and JP,59-137062,A controlled the outer diameter of the whole hollow filament bunch in a septum section hollow filament effective area, even if the cutback of the blood stagnation sections was completed, a header outer diameter could not be made small, and by the time it

reduced abolition cost, it had not resulted.

[0015] Moreover, although the ring which converges a thread existed in the case edge therefore, in the manufacturing process, thread insertion into a case became comparatively difficult, and wearing of a ring had taken time and effort.

[0016] Moreover, since a hollow fiber module which is indicated by JP,63-9448,A or announcement JP,60-500083,A can make a header small, it is connected with a blood stagnation section cutback or abolition cost reduction, but on the gestalt of the case, since it has the annulus ring-like undercut section, it needs to form a case by the blow molding method inevitably. By these blow molding method, a problem occurs based on the data in the inclination out of which a size does not come to accuracy, some other fabricating methods, for example, injection-molding method generally used. That is, dimensional accuracy is bad, and, as for the case which carried out blow molding, causes confusion of a production line by the poor assembly by size fluctuation or thick nonuniformity, or seal nature produces a faulty product.

[0017] Moreover, it is dramatically difficult on the shaping to form the usually formed baffle, in order that B liquid may enable it to distribute to the whole hollow filament bunch by B liquid induction at abbreviation homogeneity. In addition, it is also difficult to form the screw well used as a means to attach a header in a case, a header anchoring means has the problem of **, such as being limited to the method of the welding by parenchyma, the ultrasonic wave, a solvent, etc., or adhesion, and it was not put in practical use substantially.

[0018] In view of the trouble of the above-mentioned conventional technology, the object of this invention has little stagnation section, and the miniaturization by the formation of a header byway is possible for it, and, moreover, it is in the thing with sufficient dimensional accuracy for which a utilizable hollow fiber module and its manufacture method are offered industrially by low cost.

[0019]

[Means for Solving the Problem] That the above-mentioned object should be attained, as a result of this invention persons' inquiring wholeheartedly, this invention shown below was reached. (1) -- with case drum section material which has tubed idiosoma equipped with a side nozzle which contains a ***** hollow filament bunch and this hollow filament bunch, and opens two or more hollow filaments for free passage to a peripheral face of this hollow filament bunch [namely,] In a hollow fiber module which has said case drum section material, a septum which fixed the edges of said hollow filament bunch, and header material which clung to ends of said case drum section material equipped with an edge nozzle in the condition of carrying out the opening of the ends of said hollow filament bunch A hollow fiber module characterized by joining case edge material which has a header joint for engaging with a thread bundle regulating part which regulates an appearance configuration of said hollow filament bunch, and said header material at least to said case drum section material edge.

[0020] (2) A bore (D1) of said thread bundle regulating part is a hollow fiber module given in said 1 characterized by there being a value of a constant k expressed with the following type within limits which satisfy the range of 0.45-0.55.

[0021] $k = d^2 \times n / D^2$ however an outer diameter (micrometer) of d: hollow filament, and a number (3) of n: hollow filament -- a hollow fiber module given in either [which is characterized by preparing a thread bundle guide part in said case edge material / said] 1-2.

[0022] (4) A hollow fiber module given in either [which is characterized by having an annular seal member in said case edge material and header joint, and making variation of tolerance (D2-D1) of a bore (D2) of this annular seal member, and said thread bundle regulating part bore D1 them in the range of 0.5mm - 1.5mm / said] 1-3.

[0023] (5) A hollow fiber module given in either [to which said case drum section material and said case edge material are characterized by being obtained by injection molding / said] 1-4.

[0024] (6) A hollow fiber module given in either [to which said case drum section material and said case edge material are characterized by being joined by ultrasonic bonding / said] 1-5.

[0025] (7) A hollow fiber module given in either [which is characterized by using for blood purification / said] 1-6.

[0026] (8) A dialyzer characterized by including a hollow fiber module of a publication in either [said] 1-7.

[0027] (9) To both ends of case drum section material which has tubed idiosoma equipped with a side nozzle After joining case edge material which has at least a thread bundle regulating part and a header joint which regulate an appearance configuration of said hollow filament bunch and assembling a main part case, Two or more hollow filaments are inserted in this main part case. Each edge of this hollow filament A manufacture method of a hollow fiber module characterized by joining header material which formed a septum to which adhesion immobilization was carried out with a sealing agent at this main part case, and the opening of this hollow filament is carried out, and was equipped with an edge nozzle subsequently to both ends of this main part case.

[0028]

[Embodiment of the Invention] It explains based on the drawing in which the example of a gestalt of operation of this invention is shown.

[0029] Drawing 1 is the side elevation showing an example of the member which constitutes the main part case of the hollow fiber module which it is a cross-section side elevation a part, drawing 2 is the important section enlarged view of drawing 1 , and drawing 3 requires for this invention which shows an example of the hollow fiber module concerning this invention.

[0030] If drawing 1 is referred to, the case edge material 2 to the ends of the case drum section material 1 in namely, the tubed main part case 3 joined by ultrasonic bonding, respectively Contain the hollow filament bunch 4 and it fixes to the main part case 3 in the condition of carrying out the opening of the ends of the hollow filament bunch 4 by the septum 5. the header material 6 which has the nozzle 61 (edge nozzle) for A liquid, and the blood room 62 to the ends of the main part case 3 -- the annular packing 7 -- minding -- liquid -- it is one example of the hollow fiber module of this invention densely joined to the main part case 3. Here, the case drum section material 1 is equipped with the tubed idiosoma 11, the side nozzle 12 for B liquid, a baffle 13, and B liquid induction 14. if drawing 2 is referred to -- this Fig. -- the important section of drawing 1 -- expanding -- the case edge material 2 -- a thread bundle regulating part 22 and the header joint 23 -- having -- **** -- the case drum section material 1 -- the ultrasonic-bonding section 8 -- liquid -- it is joined densely. Moreover, in this example, it is considering as the configuration which has a thread bundle guide part 21 at the case edge material 2.

[0031] Reference of drawing 3 divides and expresses the main part case 3 used for the hollow fiber module of this invention to the case drum section material 1 and the case edge material 2 so that it may be easy to understand.

[0032] When drawing 4 is referred to, it is an example of the conventional hollow fiber module 9 with the hollow filament bunch 4, the tubed main part case 3 where it has the side nozzle 12 which contained the hollow filament bunch 4 and was open for free passage on the outside surface of a hollow filament, the septum 5 that fixed the ends of this hollow filament bunch 4 in the condition of carrying out a opening, and the header material 6 attached in the ends of this main part case 3.

[0033] although screwing with the screw through ultrasonic bonding, adhesion by the solvent, spin welding, and a sealant etc. is employable [using drawing,] in drawing 1 here, for example as a cementation means for joining the case edge material 2 to the ends of the case drum section material 1, respectively if the hollow fiber module of this invention is further explained to details -- anyway -- liquid -- it is important to consider as the means which can carry out a seal densely. An activity is easy and ultrasonic bonding is the most desirable than the short means of working hours is industrially excellent.

[0034] The case drum section material 1 equips the ends of idiosoma with the side nozzle 12, the baffle 13, and B liquid induction 14 for B liquid further, respectively, when it has the tubed idiosoma 11 which contains a hollow filament bunch and uses it especially for a medical-application way, as it is shown in drawing 3 .

[0035] In drawing 2 , as for the thread bundle guide part 21 prepared in the case edge material 2, it is desirable to form the tilt angle theta for thread insertion, and it is [the angle theta] desirable to consider

as the range of 10-45 degrees.

[0036] Moreover, although this **** riser section is based also on the physical properties of a hollow filament, or the physical properties of potting material in the so-called potting material **** riser section of the portion which the hollow filament bunch 4 could crawl on 21-near thread bundle guide part ' from the septum 5 exactly, and came out, and the hollow filament bunch 4 Generally, since there is no reinforcement comparatively [upright], when this **** riser section had touched or adhered to the case and an oscillation, an impact, etc. are added, it is the portion which is the easiest to undergo a deficit. Therefore, it is desirable to prepare the annular space where a hollow filament does not exist substantially, as a hollow filament bunch and a fixed gap open 21-near thread bundle guide part '.

[0037] As for the thread bundle regulating part 22 prepared in the case edge material 2, in drawing 2, it is desirable to give a radius of circle so that breakage may not be done to a thread. Moreover, a thread bundle regulating part 22 has a desirable direction near the hollow filament effective area prepared in the septum 5 as much as possible so that the size regulation effect can fully be demonstrated.

[0038] In addition, the inside diameter (D1) of a thread bundle regulating part 22 becomes settled by the outer diameter of a hollow filament, the number of a hollow filament, and the constant k.

[0039] It is put in another way as a constant k being the filling factor of the hollow filament in a thread bundle regulating part 22. As a result of this invention persons' repeating an experiment, it finds out that the range of 0.45-0.55 has a proper constant k. A constant k is for asking for the cross section on the appearance at the time of on the whole seeing a hollow filament bunch, and the bore area of a thread bundle regulating part 22 and the cross section on the appearance of the hollow filament bunch 4 whole are made substantially in agreement, and it becomes possible for there to be nothing also strongly, for there to be also loosely and to pinch the hollow filament bunch 4 by the thread bundle regulating part 22.

[0040] Namely, if a constant k is smaller than 0.45, it will put in another way and a filling factor is small. Since a bias occurs in the hollow filament bunch 4, or the shape of an appearance of the hollow filament bunch 4 whole becomes an abbreviation ellipse form and big path clearance more than fixed can be performed between a header bore and the periphery portion of the hollow filament bunch 4 whole. It becomes easy to produce **** by stagnation of a blood flow, and the blood of this portion become easy to **** in the blood room 62 in a header in the case of the autotransfusion.

[0041] Moreover, if a constant k was larger than 0.55 and it would put in another way, when the filling factor was too high and potting is carried out even if were hard coming to do a thread insertion activity, the hollow filament scraped at the time of insertion, and it becomes easy to be damaged and insertion was completed, it becomes easy for defects, such as un-permeating and a hollow filament crack, to generate.

[0042] In drawing 2, as a cementation means, although which means is sufficient as screwing with ultrasonic bonding, adhesion by the solvent, spin welding, and a screw, fitting of heights and a crevice, etc., anyway, since the short means of working hours is industrially excellent, it is desirable [the header joint 23 prepared in the case edge material 2 is easy to work, and].

[0043] Moreover, it is more desirable to have the annular packing member 7 which consists of elastic bodies, such as silicone rubber, also in order to minimum-ize the blood stagnation section of the blood room 62 in a header in the example of drawing 1 although the annular packing member 7 is not necessarily required since the header joint 23 can offer a sealing seal suitable for the blood passage which passes along the inside of a header depending on the cementation means.

[0044] Here the bore (D2) of the annular packing member 7 As a result of it is important to consider as the size which does not plug up opening of the hollow filament by which the opening was carried out to the septum 5 and this invention persons' inquiring wholeheartedly, the deformation of this annular packing member 7, the dimensional tolerance of each part material, etc. are taken into consideration. The result with desirable it being the range whose D2-D1 is 0.5mm - 1.5mm was obtained to the bore (D1) of a thread bundle regulating part 22. That is, there is a possibility of plugging up the opening of a hollow filament as D2-D1 is 0.5mm or less, and it is become easy to produce stagnation of blood that D2-D1 is 1.5mm or more.

[0045] Although especially the construction material of the case drum section material 1 which constitutes the main part case 3 of the hollow fiber module of this invention shown in drawing 3, and the case edge material 2 is not limited, it is desirable that it is general-purpose plastics, in view of cost or safety. As general-purpose plastics, polystyrene, a polycarbonate, PMMA, polyethylene, polypropylene, ABS, AS, etc. are mentioned.

[0046] Moreover, the case drum section material 1 and the case edge material 2 of this invention article are the feature with bigger being obtained by injection molding than the configuration. It is because what dimensional accuracy was comparatively good, and was stabilized, could produce by low cost, and was excellent in the industrial target is obtained according to injection molding.

[0047] Moreover, since the manufacture method of this invention article can carry out cementation to the case drum section material 1 and the case edge material 2 which constitute the main part case 3 not at the inside of the manufacturing process of a hollow fiber module but at the prior process which exists independently, it has the feature that it can adopt without changing the manufacturing process of a certain hollow fiber module in any way conventionally.

[0048] Although the hollow fiber module of this invention is applicable to the use for which the conventional hollow fiber module is used, using for blood purification is more desirable than the feature and effect. It is most desirable to include in a dialyzer and to use it as an artificial kidney especially.

[0049]

[Example]

14400 PMMA hollow filaments for one to example 2 hemodialysis (outer diameter of 260micro) are used. It manufactures on the conditions which show the hollow fiber module of this invention shown in drawing 1 in a table 1. After circulating through 1l. of cow fresh blood of 40% of hematocrit values for 10 minutes by the rate of flow of 200 ml/min using this As a result of doing the autotransfusion activity which supplies a 100ml physiological saline by the rate of flow of 100 ml/min, subsequently supplies air, and extrudes the liquid in a hollow filament, the result of a table 1 was obtained.

[0050] The conventional hollow fiber module shown in drawing 4 was manufactured using the same hollow filament bunch used in the example of comparison 1 examples 1-2. It was similarly shown in a table 1 in order to compare a result with said example etc.

[0051] However, in order that there might be no thread bundle regulating part D1 in the conventional hollow fiber module, the bore in the idiosoma of a main part case showed D1 in a table.

[0052] In addition, the bore in the edge of a main part case was phi 58.

[0053] It turns out by making small difference D2-D1 of the thread bundle regulating part bore of the hollow fiber module of this invention, and an annular packing bore that it decreases **** in a blood room so that the result of this table 1 may show.

[0054] Although **** in a blood room also tended to happen, and the hollow filament closed with the structure the conventional hollow fiber module shown in the example 1 of a comparison and it was not generated about thread according to it this time, either, it may happen from the bore in the edge of a main part case being phi 58 enough structurally, and closes on a manufacturing process, and the inspection about thread is indispensable.

[0055]

[A table 1]

	D 1	定数 k	D 2	D2-D1	中空糸束 の挿入性	血液室における 残血の有無	中空糸の 塞ぎ糸の有無	ヘッダー の外径	効果の 判 定
実施例 1	46.5	0.45	47	0.5	良	無し	無し	φ64	○
実施例 2	46	0.46	47	1	良	無し	無し	φ64	○
比較例 1	(46.5)	—	50	4.5	良	有り	無し	φ71	×

[0056]

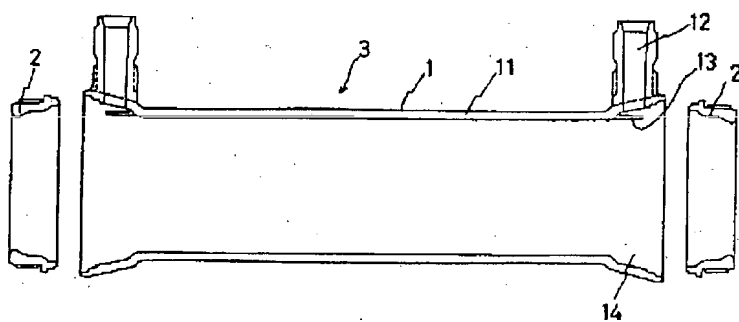
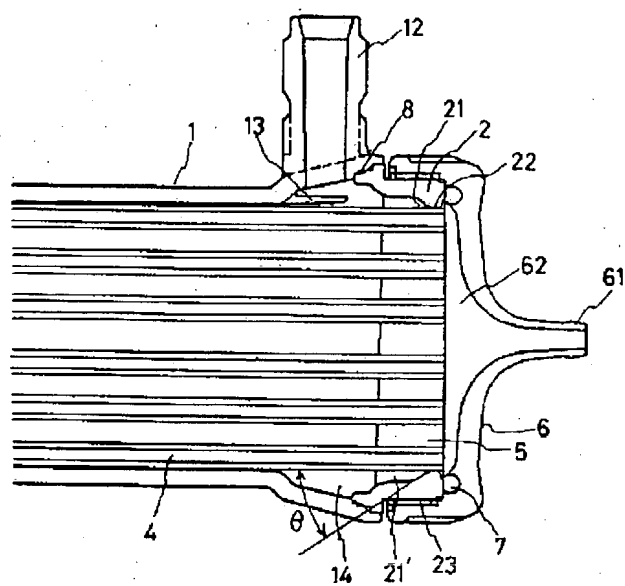
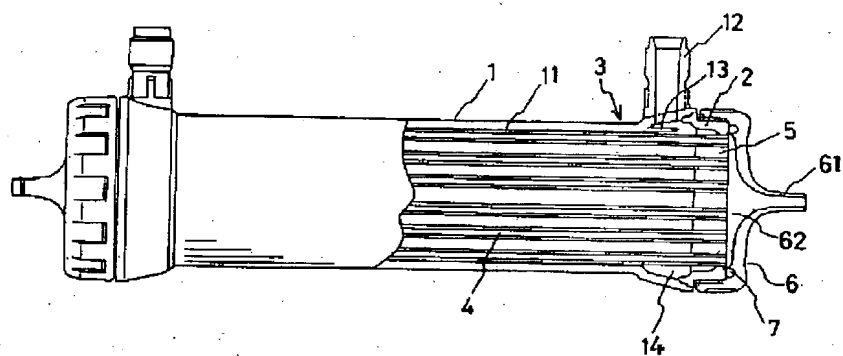
[Effect of the Invention] When it uses for the artificial kidney of medical application, can lose the blood stagnation section in a header, and can prevent **** of the opening of a hollow filament, and the miniaturization of a header is attained, and since the hollow fiber module of this invention can miniaturize the whole hollow fiber module, it can reduce medical-application trash.

[0057] Moreover, since the capacity of a header inner surface and a blood room can be decreased and the blood rate of flow within each hollow filament is made to abbreviation homogeneity, **** after the improvement in dialysis effectiveness and dialysis is improved.

[0058] Furthermore, since each part material can be obtained with injection molding, it can obtain the product which was excellent in the industrial target with sufficient dimensional accuracy with low cost.

[0059] As mentioned above, the module of this invention has little stagnation section, and since it can miniaturize, it is applicable to the hollow fiber module of any uses.

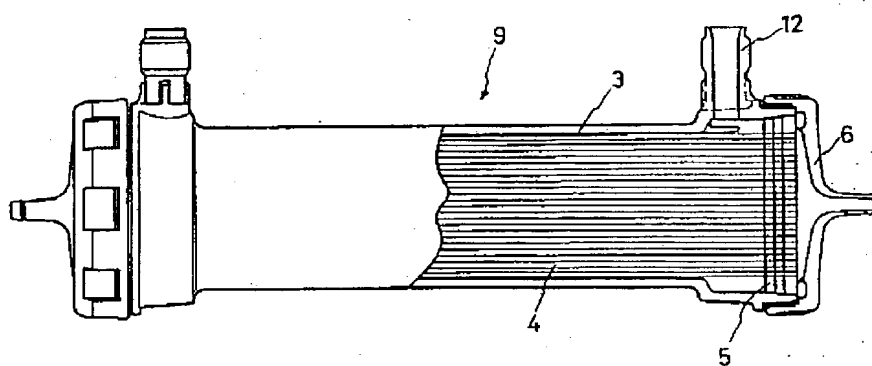
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